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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,785	02/16/2001	Tadamitsu Kishimoto	046124-5042	1146

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MORGAN LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20004

EXAMINER

NICKOL, GARY B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 09/04/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/646,785

Applicant(s)

KISHIMOTO ET AL.

Examiner

Gary B. Nickol Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1, 5, 9, 12, and 14 drawn to the special technical feature of a therapeutic agent that inhibits SDF-1.

Group 2, claim(s) 1, 5, 10, 15, and 17, drawn to the special technical feature of a therapeutic agent that inhibits CXCR4.

Group 3, claim(s) 1, 5, 11 and 13, drawn to the special technical feature of a therapeutic agent that inhibits CXCR4 in antagonistic competition with SDF-1.

Group 4, claim(s) 1, 5, 10, 16, and 18, drawn to the special technical feature of a therapeutic agent that inhibits SDF-1 from binding to CXCR4 by binding to CXCR4.

Group 5, claim(s) 1, 6, 19, drawn to the special technical feature of a therapeutic agent comprising a substance which inhibits signaling from CXCR4 to nuclei.

Group 6, claim(s) 1, 7, 20-21 drawn to the special technical feature of a therapeutic agent comprising a substance which inhibits the expression of CXCR4.

Group 7, claim(s) 1, 8, 22-23 drawn to the special technical feature of a therapeutic agent comprising a substance which inhibits the expression of SDF-1.

Group 8, claim(s) 24 drawn to the special technical feature of a method for suppressing vascularization in a mammal comprising administering a substance that inhibits the action due to CXCR4.

Group 9, claim(s) 25 drawn to the special technical feature of a method for treating a solid cancer in a mammal comprising administering a substance that inhibits the action due to CXCR4.

Art Unit: 1642

Group 10, claim(s) 26 drawn to the special technical feature of a method for treating a disease in a mammal comprising administering a substance that inhibits the action due to CXCR4.

Group 11, claim(s) 27 drawn to the special technical feature of a method for repairing a tissue in a mammal comprising administering a substance that inhibits the action due to CXCR4.

Group 12, claim(s) 2 drawn to the special technical feature of a therapeutic agent for a solid cancer comprising a substance that inhibits the action due to CXCR4.

Group 13, claim(s) 3 drawn to the special technical feature of a therapeutic agent for a disease comprising a substance that inhibits the action due to CXCR4.

Group 14, claim(s) 4 drawn to the special technical feature of a therapeutic agent for repairing a tissue comprising a substance that inhibits the action due to CXCR4.

The inventions are distinct, each from the other because of the following reasons:

A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. Unity of invention is fulfilled only when there is a technical relationship among the inventions involving one or more of the same or corresponding special technical features which define a contribution over the prior art. If there is no special technical feature, if multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(d).

The inventions listed as Groups 1-14 do not relate to a single inventive concept under PCT Rule 13.1 because under PCT Rule 13.2 they lack the same or corresponding special technical features for the follow reasons;

Art Unit: 1642

The technical feature linking Groups 1-14 appears to be agents which interfere with the action of CXCR4. However, Murakami *et al.* (J.Exp.Med., Vol. 186, No. 8, 1997) teach a small molecule, T22, which is a CXCR4 inhibitor (abstract). Although, Murakami *et al.* do not teach that the agent is useful for inhibiting vascularization, the claims read on the active ingredients *per se*, an agent that inhibits the action due to CXCR4. Further, a composition is a composition irrespective of what its intended use is. See In re Tuominen, 213 USPQ 89 (CCPA 1982).

Hence, the technical feature linking the inventions of Groups 1-14 do not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the prior art. Accordingly, Groups 1-14 are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept and restriction for examination purposes as indicated is proper.

Species Requirement:

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Claim 13:

- a) SDF-like proteins including fusions thereof
- b) a low molecular weight compound

Claim 14:

- a) anti-SDF-1 antibodies and fragments thereof

Art Unit: 1642

- b) a fusion protein possessing binding activity to SDF-1
- c) a low molecular weight compound capable of binding to CXCR4

Claim 17:

- a) CXCR4-like proteins including fusions thereof
- b) a low molecular weight compound

Claim 18:

- a) anti-CXCR4 antibodies and fragments thereof
- b) a substance that induces a structural change in SDF-1
- c) a low molecular weight compound capable of binding to SDF-1-binding site

Claim 19:

- a) a MAPK cascade inhibitor
- b) a phospholipase C inhibitor
- c) a PI3 kinase inhibitor

Claim 21:

- a) an antigene
- b) an antisense polynucleotide or antisense RNA
- c) a ribozyme
- d) an inhibitor against the expression control site of XCCR4

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The products of the above species represent separate

Art Unit: 1642

and distinct molecules with different structures and functions such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Art Unit: 1642

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
September 3, 2002

